

**REMARKS/ARGUMENTS*****Status of Claims***

Claims 1 and 16 have been amended.

Claims 8, 9, and 17 have been canceled.

Claims 18-20 have been withdrawn.

Thus, claims 1-7 and 10-16 are currently pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed application.

***Claim Amendments***

Claim 1 has been amended to read:

1. A transdermal spray formulation comprising:
  - a) a pharmaceutically active agent;
  - b) 0.1% to about 5.0% by weight VP/VA copolymer;
  - c) **at least 60% by weight ethanol**; and
  - d) optionally a penetration enhancer, which, if present, is present in an amount of 0.01% to 5.0% by weight of the composition.

*See supra* claim 1 (emphasis added to indicate amending language). Support for the amending language is found in the specification. *See* Application at ¶ [0032].

Claim 16 has been amended to read:

16. A transdermal spray formulation according to claim 1 for forming a patch on the skin of a subject, wherein the optional penetration enhancer, when present, is different to ethanol.

*See supra* claim 16. Support for the amending language is found in the specification. *See* Application at ¶¶ [0039]-[0040].

**Claim Rejections – 35 U.S.C. § 102**

Claims 1-4, 6-9, and 11-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 00/45795 to Wain *et al.* (hereinafter “Wain”). Claims 2-4, 6-7, and 11-16 depend from independent claim 1, and claims 8, 9, and 17 have been canceled. Thus, claims 2-4, 6-7, and 11-16 stand or fall on the application of Wain to independent claim 1. “A claim is anticipated only if each and every element **as set forth in the claim** is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP § 2131.

Applicants respectfully submit that Wain does not anticipate claims 1-4, 6-7, and 11-16 because Wain does not describe each and every element as set forth in independent claim 1. See *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d at 1053. Applicants respectfully submit that Wain fails to anticipate claims 1-4, 6-7, and 11-16 because Wain fails to teach a transdermal spray formulation comprising **0.1% to about 5.0% by weight VP/VA copolymer** and **at least 60% by weight ethanol**. See Wain at 11-16 (Examples 1-12).

**Claim Rejections – 35 U.S.C. § 103**

Claims 1-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wain in view of Mariana Foldvari, *Non-invasive administration of drugs through the skin: challenges in delivery system design*, CHEMICAL ENGINEERING (December 12, 2000) (hereinafter “Foldvari”). Claims 2-7 and 10-16 depend from independent claim 1 and, as noted above, claims 8, 9, and 17 have been canceled. Thus, claims 2-7 and 10-16 stand or fall on the application of the combination of Wain and Foldvari to independent claim 1. As noted by the United States Supreme Court in *Graham v. John Deere Co. of Kansas City*, an obviousness determination begins with a finding

that **“the prior art as a whole in one form or another contains all” of the elements of the claimed invention.** See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 22 (U.S. 1966).

As explained in the previous section regarding rejections under 35 U.S.C. § 102, *Wain* does not disclose all of the elements of the instant invention, and the Final Office Action does not cite *Foldvari* as to overcome the shortcomings of *Wain*. As such, the Final Office Action’s combination of *Wain* and *Foldvari* do not render obvious claims 1-7 and 10-16.

Based on the foregoing, Applicants respectfully submit that claims 1-7 and 10-16 are presented in condition for allowance.

**CONCLUSION**

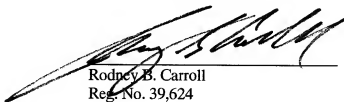
Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections and objections is respectfully requested by the Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Final Office Action dated December 1, 2008 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,

Date: \_\_\_\_\_

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